Supreme Court, U.S.
FILED
MAR 26 1996
CLERK

(2)

No. 95-1384

In The

Supreme Court of the United States

October Term, 1995

SMITH & NEPHEW DYONICS, INC.,

Petitioner,

v.

RUSSELL VIOLETTE,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

RESPONDENT'S BRIEF IN OPPOSITION

RANDALL E. SMITH
(Counsel of Record)
JOHN H. O'NEIL, JR.
SMITH ELLIOTT SMITH
& GARMEY, P.A.
199 Main Street
P.O. Box 1179
Saco, Maine 04072
(207) 282-1527

Counsel for Respondent

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

27 pp

QUESTION PRESENTED

Whether the First Circuit Court of Appeals erred in holding that federal preemption is an affirmative defense which was waived by the Defendant by failing to raise the issue or present evidence of Food and Drug Administration (FDA) review at the trial court level.

TABLE OF CONTENTS

Page(s)

QUESTION PRESENTED i

STATEMENT OF THE CASE 1

A. The Court of Appeals' Opinion 3

B. Significance of 510(k) Approval 4

REASONS FOR DENYING THE WRIT 5

I. THERE IS NO CONFLICT BETWEEN THE DECISION OF THE FIRST CIRCUIT COURT OF APPEALS AND THE DECISIONS OF THE SUPREME COURT, THE CIRCUIT COURTS OF APPEALS OR STATE COURTS CONCERNING THE ISSUE OF WHETHER THE FAILURE TO RAISE FEDERAL PREEMPTION BEFORE THE TRIAL COURT RESULTS IN A WAIVER 5

II. THIS CASE DOES NOT PRESENT AN IMPORTANT FEDERAL QUESTION AND THE ISSUE INVOLVED IN THIS CASE IS DISSIMILAR TO THE ISSUE INVOLVED IN *MEDTRONIC, INC. v. LOHR* 8

CONCLUSION 12

APPENDICES ..... App. 1

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) . . 10, 11

Committee of Dental Amalgram Alloy Manufacturers v. Henry, 871 F. Supp. 1278 (S.D. Cal. 1994) 6

Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir.), *petition for cert. filed*, 64 U.S.C. W. 7

Feldt v. Mentor Corp., No. H-93-2205 (S.D. Tex. July 11, 1994) 7

Fitzgerald v. Mallinckrodt, Inc., 681 F. Supp. 404 (E.D. Mich. 1987) 6

Ignace v. International Playtex, Inc., No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. August 14, 1987) 6

International Longshoremen's Association v. Davis, 476 U.S. 380 (1986) 3, 5

Kennan v. Dow Chemical Co., 717 F. Supp. 799 (M.D. Fla. 1989) 6

Kennedy v. Collagen Corporation, 67 F.3d 1453 (9th Cir. 1995) 10

Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995) 4, 8, 9, 10

Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) 6, 7, 9

Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) 7

Sweeney v. West Vaco Company, 926 F.2d 29 (1st Cir. 1991), *cert. denied*, 502 U.S. 899 (1991) 3

Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995) 9

TABLE OF AUTHORITIES – Continued

Page

Talbott v. C.R. Bard, Inc., 865 F. Supp. 37 (D. Mass. 1994) 7

Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8 (1st Cir. 1995) 3, 6, 7, 9

STATE CASES

Haudrich v. Howmedica, No. 78319, 1996 Ill. LEXIS 8 (Ill. S. Ct. Jan. 18, 1996) 5, 6

Pratt v. O'Hara, 190 A. 622 (Me. 1937) 11

FEDERAL STATUTES

21 U.S.C. § 360c(I)(1)(A)(ii)(I) 5

21 U.S.C. § 360K(a) 10

21 U.S.C. § 360k 10

MISCELLANEOUS

21 C.F.R. § 807.97 4

21 C.F.R. § 808.1(d) 10

Supreme Court Rule 15.1 8

STATEMENT OF THE CASE

On December 22, 1992, Respondent Russell Violette served Smith & Nephew Dyonics, Inc. (hereinafter referred to as "Dyonics") with a complaint filed against it in the Kennebec County Superior Court in the State of Maine. The Complaint alleged negligence, breach of warranty and that Dyonics' product was defective, both in design and for failure to provide surgeons with appropriate warnings and instructions. The product was a carpal tunnel surgery kit manufactured by Dyonics. Dyonics removed the case to the United States District Court for the District of Maine and answered the complaint. Dyonics pled federal preemption as an affirmative defense, but at no time prior to trial filed a motion for summary judgment on this issue. In its pretrial memorandum, Dyonics did not mention preemption as a controverted point of law, nor did Dyonics assert preemption in its trial brief or in its numerous motions *in limine*.

In January of 1994, a trial was held on the claims for defective design, negligence and the failure to provide warnings and instructions. The evidence adduced at trial established that Dyonics failed to provide surgeons with adequate information concerning the nature and extent of complications associated with this surgery and greatly oversimplified the ease with which this surgery could be learned. The evidence also proved that Russell Violette had sustained permanent damage to his hand as a result of this surgery.

There was no evidence presented at trial that the Defendants' product was a medical device requiring FDA review. There was no evidence that the product, its

instructions or packaging were the subject of FDA review. Finally, there was no evidence that the product, its instructions or packaging received any form of FDA approval. In fact, the Defendant vigorously and successfully sought the exclusion of evidence with regard to interaction between the Defendant and the FDA. The jury returned a verdict in favor of Russell Violette and awarded him $250,000.00 in damages.

Judgment was entered on January 31, 1994, and Dyonics made motions for judgment notwithstanding the verdict and for a new trial which were denied. In neither the Motion for Judgment Notwithstanding the Verdict nor in the Motion for a New Trial was federal preemption mentioned or brought to the attention of the trial court. A final amended judgment was entered on March 16, 1994.

The Defendant filed a Notice of Appeal on March 17, 1994. As a part of the appendix filed with the First Circuit Court of Appeals, the Defendant included copies of two letters purported to be from the FDA. These letters have never been authenticated nor has foundational material ever been generated to indicate they would have been admissible evidence. Substantively, all these letters say is that the Defendant may sell a product but that fact does not mean " . . . that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA." (Appendix A). It was on the basis of these letters that Dyonics advanced federal preemption as an issue, for the first time, before the First Circuit Court of Appeals.

A. The Court of Appeals' Opinion

The First Circuit held that Dyonics had waived its preemption defense by raising it substantively for the first time only after trial. The First Circuit made note that Dyonics had numerous opportunities to raise this issue and stated:

> it is plain that preemption flickered but once, dimly, on the radar screen of this litigation and then disappeared forever, abandoned by Dyonics, depriving the magistrate judge of his rightful opportunity to address the question in the first instance.

Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 11 (1st Cir. 1995). The Court held that there were no exceptional circumstances which would justify deviation from the traditional rule that affirmative defenses must be presented for the scrutiny of the District Court. *Id.*

The First Circuit reasoned that any Food, Drug and Cosmetic Act (FDCA) preemption was similar to preemption under the Labor Management Relations Act (LMRA), which was discussed in *Sweeney v. West Vaco Company*, 926 F.2d 29 (1st Cir. 1991), *cert. denied*, 502 U.S. 899 (1991). *Violette*, 62 F.3d at 10, 11. *Sweeney* held that preemption under the Labor Management Relations Act was an affirmative defense that was not jurisdictional and could be waived by failure to appropriately present it to the District Court. The First Circuit distinguished *International Longshoremen's Ass'n v. Davis*, 476 U.S. 380 (1986), from *Sweeney* and from this case because it involved a "choice of law" question rather than a "choice of forum" question. *Violette*, 62 F.3d at 11, 12.

In *Davis*, the Supreme Court held that the creation of the National Labor Relations Board as an adjudicatory forum to decide cases involving the National Labor Relations Act was intended by Congress to supplant the authority of state courts and United States District Courts, sitting in diversity, to decide labor union issues. Since Congress did not intend to supplant the United States District Courts, sitting in diversity, or state trial courts from deciding the applicability of this affirmative defense to traditional state law tort and product liability claims, preemption was a defense which could be waived.

B. Significance of 510(k) Approval

The Petitioner in Part A to its Statement of the Case discusses at length the Medical Device Amendments to the FDCA, 21 U.S.C. § 360, *et seq.* (1994). While the Respondent does not significantly disagree with the description by the Petitioner of the first two avenues for a device review and approval, Dyonics vastly overstates the significance of 510(k) approval regarding medical device safety. The letters which Dyonics relies upon state that Dyonics may not claim that its endoscope for carpal tunnel surgery has been FDA approved. This is consistent with the FDA's regulations, which note that approval of a device under § 510(k) procedures as the substantial equivalent to a grand-fathered device "does not in any way denote official approval of the device", 21 C.F.R. § 807.97.

As noted in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), the FDA could hardly find a device as safe and effective as a grand-fathered device, whose safety and

effectiveness had never been established by FDA procedures. *See* 21 U.S.C. § 360c(I)(1)(A)(ii)(I).

The focus in this case must be upon the real case or controversy which presents itself to this Court. This case does not present the opportunity for the Supreme Court to issue a broad declaration on what Congress intended the scope of the FDCA to be. The limited issue before this Court is whether or not the First Circuit erred in holding that preemption is an affirmative defense which may be waived if not raised before the trial court.

REASONS FOR DENYING THE WRIT

I. THERE IS NO CONFLICT BETWEEN THE DECISION OF THE FIRST CIRCUIT COURT OF APPEALS AND THE DECISIONS OF THE SUPREME COURT, THE CIRCUIT COURTS OF APPEALS OR STATE COURTS CONCERNING THE ISSUE OF WHETHER THE FAILURE TO RAISE FEDERAL PREEMPTION BEFORE THE TRIAL COURT RESULTS IN A WAIVER.

There is no United States Supreme Court decision dealing with the issue of waiver in the context of the FDCA. Similarly, there are no other decisions on this issue in any of the Circuit Courts of Appeals. The issue has been raised at the state court level. In *Haudrich v. Howmedica*, No. 78319, 1996 Ill. LEXIS 8 (Ill. S. Ct. Jan. 18, 1996), the Supreme Court of Illinois ruled that federal preemption under the FDCA was in the nature of an affirmative defense which was waived if not presented initially in the trial court. The court in *Haudrich* distinguished *International Longshoremen's Ass'n v. Davis*, and

cited with approval the *Violette* decision. The *Haudrich* Court stated:

> In the present case, however, unlike in *Davis*, Congress has not designated another forum for the resolution of disputes concerning medical devices. Although Congress has enacted a body of substantive law dealing with such devices, it has not "confided primary interpretation and application of its rules to a specific and specially constituted tribunal." (*Davis*, 476 U.S. at 389, 90 L.Ed. 2d at 399, 106 S.Ct. at 1911, quoting *Garner v. Teamsters*, (1953), 346 U.S. 485, 490, 98 L.Ed. 228, 239, 74 S. Ct. 161, 165-66.) Thus, the issue here does not involve a choice of forum but instead concerns whether State tort or Federal statutory law controls. Under these circumstances, the issue of preemption is not jurisdictional but is in the nature of an affirmative defense, subject to the traditional rules of appellate adjudication, including [*18] timely presentment of issues and waiver.

No. 78319, 1996 Ill. LEXIS at *17.

The First Circuit Court in *Violette*, 62 F.3d at 12 n.2, noted that the authority proffered by Dyonics highlighted the proposition that federal preemption should have been brought properly before the trial court. *See Kennan v. Dow Chemical Co.*, 717 F.Supp. 799 (M.D. Fla. 1989); *Fitzgerald v. Mallinckrodt, Inc.*, 681 F.Supp. 404 (E.D. Mich. 1987); *Ignace v. International Playtex, Inc.*, No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. August 14, 1987). (In each of these cases preemption was raised in the context of summary judgment). *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (summary judgment); *Committee of Dental Amalgram Alloy Mfrs. v. Henry*, 871 F.Supp. 1278, 1285 (S.D. Cal.

1994) (summary judgment); *Talbott v. C.R. Bard, Inc.*, 865 F.Supp. 37 (D. Mass. 1994) (motion to dismiss); *Feldt v. Mentor Corp.*, No. H-93-2205, slip op. at 1-2, 10 (S.D. Tex. July 11, 1994).

Violette noted that the issue of whether state tort or federal statutory law controls is a classic "choice of law" question and subject to determination by the trial court. Congress did not intend to remove that choice of law issue from the trial court and, accordingly, it could be waived when not appropriately presented. *Violette*, 62 F.3d at 11, 12.

It is also important to recognize that subject matter jurisdiction is a legal term of art. The Circuit Courts of Appeals decisions, which were cited by the Petitioner do not mention subject matter jurisdiction. *See, e.g., Mendes v. Medtronic, Inc.*, 18 F.3d at 14. ("Congress enacted the MDA to give the [FDA] comprehensive control over medical devices for the first time."); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 395 (4th Cir.), *petition for cert. filed*, 64 U.S.C.W. (Dec. 22, 1995) (No. 95-1010) ("Congress established a scheme for comprehensive regulation of medical devices . . . "); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992). The dicta in these cases speaks of control over medical device regulation, not preemption and not choice of forum. If Dyonics wished to avail itself of FDA protection, the trial court was the forum in which it should have done so. The forum itself did not diminish Dyonics' protection by the FDA; Dyonics did.

None of those cases mention subject matter jurisdiction or the limitation of power upon the United States

District Court to enforce, under choice of law principles, the scope of FDA power. This quite clearly is because Congress did not intend the FDA to be given the power to determine the scope of the affirmative defense of preemption. This is a classic issue for the United States District Courts, sitting in diversity, and for state courts of general trial jurisdiction.

II. THIS CASE DOES NOT PRESENT AN IMPORTANT FEDERAL QUESTION AND THE ISSUE INVOLVED IN THIS CASE IS DISSIMILAR TO THE ISSUE INVOLVED IN *MEDTRONIC, INC. v. LOHR.*

As noted by the Petitioner, this Court granted certiorari in *Medtronic, Inc. v. Lohr* on January 19, 1996, Nos. 95-754 and 95-886, a decision from the Eleventh Circuit. (*Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995)). The issue under review in *Medtronic* is the substantive scope of § 360k(a) of the FDCA. This case does not present those substantive issues. Dyonics failed to place that issue before the United States District Court.

A decision by this Court in the *Medtronic* case will not affect this present action, as preemption in the *Medtronic* case was appropriately raised before the trial court, and this Court will not be addressing the choice of law versus choice of forum issue. This case does not have broad-ranging implication to the medical device industry, as it affects only those who fail to raise the issue appropriately.

Finally, pursuant to Supreme Court Rule 15.1, the Respondent is compelled to distinguish certain assertions

of law which are contained in the Petition for Writ of Certiorari. The Petitioner claims that "[t]he Court's analysis of the MDA in *Talbot* makes clear that the scope of preemption is so extensive as to be jurisdictional in nature." Petition at p. 13 (referring to *Talbot v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995)). However, in the *Violette* decision, the First Circuit noted that *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994), made it clear that the language of the statute left open the possibility that a state may impose, establish or continue burdens identical to the federal standards, leading ineluctably to the conclusion that the statute's preemptive effect is not jurisdictional. *Violette*, 62 F3d at 12 n.2.

Even the First Circuit has left open the issue of negligent design and a negligent failure to warn claim regarding medical devices which were not marketed through the premarketed approval process, but instead were marketed under § 510(k) as substantially equivalent to existing devices. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 31 n.3 (1st Cir. 1995) (First Circuit distinguishes its holding from *Lohr v. Medtronic, Inc.*).

Since the First Circuit has yet to examine 510(k)-type devices, this issue remains an open one in the First Circuit. Ironically, had Petitioner properly brought this issue before the trial court, it would seem likely that the First Circuit would have had an opportunity to resolve that issue.

It is indisputable that the scope of federal preemption in any given case is determined by congressional intent, and that ambiguity as to that intent must be resolved "in light of the presumption against the preemption of state

police power regulations." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). The FDA regulations reiterate the narrow scope of preemption under 21 U.S.C. § 360k:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by § 521(a)[1] of the act because they are not 'requirements applicable to a device' within the meaning of § 521(a) of the act. 21 CFR § 808.1(d). (Appendix B)

The Ninth Circuit Court of Appeals has expressly noted that the Act only preempts "specific requirements applicable to a particular device." *Kennedy v. Collagen Corporation*, 67 F.3d 1453, 1459 (9th Cir. 1995). The *Kennedy* court held that product liability law is of general applicability which applies to all products and not just specifically to medical devices which are the only types of regulations preempted by the Act. *Id.* The Court noted that the fact that state common law may have an indirect effect on how products are made is not dispositive as to whether it qualifies as a specific requirement applicable to a particular device as defined. *Id.* at 1459. The Court noted that such a result would let consumers be left without any recourse for harm suffered, and that such a

---

[1] 21 U.S.C. § 360k(a)

result "flies in the face of the conventional intent behind the act: consumer protection." *Id.* The Court added: "premarket approval is supposed to benefit consumers, not create a rose garden free from liability for manufacturers." *Id.* at 1460.

The Plaintiff's verdict in this case was also based upon a separate and independent claim that the Defendant was negligent in the way it taught Plaintiff's surgeon to utilize the product. In fact, Plaintiff's surgeon testified that he did not learn of certain dangers presented by using the product or that there was a safer and easier way to perform the procedure with the product until after Russell Violette was injured. Dyonics had assumed this duty by providing instructional material, videotapes and sponsoring training seminars. The duty to teach the appropriate technique associated with this product is not an issue that is governed by the FDA. Under Maine law, the assumption of this duty carried with it the requirement that the duty be exercised responsibly. *Pratt v. O'Hara*, 190 A. 622 (Me. 1937). The jury found that Dyonics did not exercise that duty responsibly.

This Court noted in *Cippolone v. Liggett Group, Inc.*, 505 U.S. at 526 (1992), that the assumption of additional duties by a manufacturer, such as an express warranty, can voluntarily take the manufacturer outside the protection of preemption and subject to requirement that the duty assumed be performed responsibly.

Finally, as noted in *Lohr v. Medtronics*, 510(k) approval was not an examination of the efficacy of this device, and 510(k) approval was not intended by Congress to have any preemptive effect with respect to state

law claims regarding product design and failure to warn claims.

CONCLUSION

The real issue in this case is whether or not Congress intended the United States District Courts and state trial courts to be divested of subject matter jurisdiction to determine the applicability of federal preemption as an affirmative defense. This is a choice of law issue. The FDA was not intended by Congress to be the forum in which these issues of law were to be decided. The failure of Dyonics to appropriately raise this issue in the trial court, despite numerous opportunities to do so, constituted a waiver of this defense. The case or controversy properly before this Court is a very narrow one and is of insufficient importance for this Court to grant the Petition For Writ of Certiorari. The Petition For Writ of Cetiorari should be denied.

Respectfully submitted,

RANDALL E. SMITH
(Counsel of Record)
JOHN H. O'NEIL, JR.
SMITH ELLIOTT SMITH & GARMEY, P.A.
199 Main Street
P.O. Box 1179
Saco, Maine 04072
(207) 282-1527

APPENDICES

APPENDIX A

[LOGO] DEPARTMENT OF HEALTH
& HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 29 1990

Mr. Eric Bannon
Regulatory Affairs
Manager
Smith & Nephew
Dyonics Inc.
160 Dascomb Road
Andover, Massachusetts
01810

Re: K901617
Endoscopic Carpal
Tunnel
Release System
(ECTR)
Regulatory Class: II
Dated: April 30, 1990
Received:
May 1, 1990

Dear Mr. Bannon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and

labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the *Federal Register.* Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA *approves* your device. Therefore, you may not promote or in anyway represent your device or its labeling as being *approved* by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be

obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

/s/ Carl A Larson
Carl A. Larson, Ph.D.
Director,
Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

[LOGO] DEPARTMENT OF HEALTH
& HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT 12 1990

Mr. Eric Bannon
Regulatory Affairs
Manager
Smith & Nephew
Dyonics Inc.
160 Dascomb Road
Andover, Massachusetts
01810

Re: K903620
Modified Carpal
Tunnel

Regulatory Class: II
Dated:
October 3, 1990
Received:
October 4, 1990

Dear Mr. Bannon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the *Federal Register.* Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA *approves* your device. Therefore, you may not promote or in anyway represent your device or its labeling as being *approved* by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be

obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

/s/ Carl A Larson
Carl A. Larson, Ph.D.
Director,
Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

APPENDIX B

21 CFR § 808.1(d)

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.

The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the

practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)

(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.

In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.